REMARKS

The most recent Official Action has been carefully considered. Claims 53-56 and 58-82 are currently pending and subject to examination in the present application. The claims have been recited in this office action for the examiner's ease of reference; no amendments are presented herewith.

The examiner has rejected the claims under 35 U.S.C. § 103 as being unpatentable under McNeil et al (US 5,403,549) and Lion et al. (US 6,143,088), and further in view of Heffner (US 5,437,686). Applicant's previously presented (and most general) claim 53 is directed to a novel composition consisting of:

- water;

- one or more monopersulfate compounds;

- one or more buffers, at least one of which is selected from the group consisting of alkali metal and alkaline earth metal salt forms of bicarbonate and/or carbonate; and

- one or more ketones, at least one of said ketones being selected from the group consisting of acetone, 2-butanone, 2-pentanone, 2-hydroxy-4-methyl-2-pentanone, hexafluoroacetone, trifluoroacetone, acetophenone, camphorsulfonic acid, and levulinic acid,

wherein the composition has a pH of from about 5 to about 9 and is formulated to achieve in situ generation of dioxirane.

McNeil, in his 1993 patent application which resulted in the '549 Patent, discloses his discovery that dioxiranes can be effective as a broad spectrum biocide, functioning effectively as a disinfectant and a sterilant. However, McNeil attempts and marginally succeeds with buffering his dioxirane-generating formulation. Specifically, McNeil is only able to successfully buffer the formulation at a low pH (having attempted and failed to buffer the formulation at a higher pH).

Reviewing the examples more closely, Example 1 includes three buffered formulations (Samples A-5, B-24 and B-30), each of which failed in effectively killing spore forming material. Consistent with this finding, McNeil concludes that, as regards these formulations, the "addition of buffer inhibited the bactericidal activity of the mixture." [Col. 11, lines 23-26]. McNeil goes on to test different ketones in Example 2, some of which were included in buffer formulations. In this example, he limited the amount of buffer (as further described below), and found that with a low amount of buffer (samples C-02 and C-03), no bacterial growth was found; however, when the buffer was increased in solution (sample E-07), the buffered mixture "inhibited the sporicidal activity of caroate and CSA." [Col. 11, lines 54-57]. In Example 3, McNeil found that "[t]he effect of buffer in diminishing the effectiveness of the caroate-ketone combination, noted in Examples 1 and 2, was shown to be repeatable," wherein the two buffered formulations (sample C-12 and C-14) each allowed sporicidal growth. Finally, in Example 4 McNeil once again tested buffers in his dioxirane-generating formulation; in this example he found that "monobasic potassium phosphate buffer interferes with bactericidal and sporicidal activity (sample C-14A);" but that "[a] commercially available buffer used in sample C-15N did not interfere with the activity of the dioxirane containing reaction product."

From these examples one can generally surmise that at higher concentrations or pH values, buffers inhibit the effectiveness of bactericidal activity of dioxirane-generating formulations. McNeil was only able to obtain effective dioxirane formulations using a 1% buffer solution (in Example 2), and

using a pH-4 buffer solution (in example 4). The buffer solution of Example 2 (as with the buffers included in the other examples) was a 0.5M KH_2PO_4, pH 7.4. The buffer solution of Example 4 was a Potassium biphthalate, pH 4.0.

During the telephone conference of October 28, 2008, the examiner and applicant's counsel engaged in a rough calculation of the amount of buffer in the non-inhibiting formulations of Example 2, reiterated as follows:

> **McNeil Formulation: 1% 0.5M KH_2PO_4**
> **Molar Mass of KH_2PO_4 = 136.09 g/mol**
>
> Amount of Buffer in Buffer Solution:
> 136.09 g/mole * 0.5 moles/L = 68.045 g/L
> To make a 10 ml buffered dioxirane solution of McNeil, with 1% buffer solution:
> 68.045 g/L * 1% = 0.68045 g/L = 0.0068045 g/10 mL

Because the amount of buffer in these working formulations of McNeil were within the recited range of the claims of the present invention, applicant lab-tested the McNeil formulations to determine the exact pH levels thereof. Specifically, applicant formulated two compositions to mirror the compositions of C-02 and C-03[1] of the McNeil Example 2, finding that these formulations exhibit a pH of 2.49 and 3.16, respectively. Furthermore, one can easily surmise that the pH of example C-15N would not fall within the pH range of the present claims (pH 5-9) because the buffer is specifically stated as pH 4. Thus, McNeil is only able to support a low-pH buffered, dioxirane-generating formulation in his working examples. McNeil further supports the theory that a higher pH buffered, dioxirane-generating formulation, is ineffective in inhibiting bactericidal activity.

The applicant's invention as presently claimed derives from the unexpected effectiveness of a neutral pH dioxirane-generating formulation. McNeil was unable to generate such a formulation, and through his failures teaches away from the possibility. Unexpected results such as these are surely the basis for allowable claims, discovered almost a decade after McNeil first disclosed the effectiveness of acidic dioxiranes. In all of the present claims, the applicant's invention is a buffered dioxirane composition having a pH of about 5 to about 9. This pH level is achievable based upon the combination of elements, and the selected buffer (carbonate or bicarbonate). To the extent that these carbonate buffers would be obvious substitute for the phosphate buffers in the McNeil formulation, it would be obvious only <u>not</u> to try them (based upon the failures within the McNeil formulation).

The examiner does not make this express argument in his most recent office action, but rather finds support for using a carbonate or bicarbonate buffer based upon Lion et al. The examiner argues that Lion et al. is directed to a composition used for similar purposes as the McNeil composition, and therefore it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use a buffer such as a mixture of bicarbonate and carbonate in the composition taught by McNeil et al, with a reasonable expectation of success, (with McNeil et al. teach the use of buffering agents in general).

However, McNeil teaches that buffers easily inhibits sporicidal activity in a dioxirane-generating formulation, and therefore only uses them in very acidic formulations. The formulations of Lion do not

[1] Because there was no 4HP in the lab, the applicant substituted 4HB, which has similar functionality and shouldn't result in a pH difference.

generate dioxirane. Further, while Lion does include a mixture of bicarbonate and sodium hydrogen carbonate as a buffer in solution, it makes no mention that such a buffer is equivalent to, or more preferably superior to, the potassium buffers in McNeil. Thus, one skilled in the art has no teachings from Lion applicable to successful buffer choices, to apply to the buffer-sensitive dioxirane generating formulation of McNeil. For these reasons applicant respectfully requests that the examiner reconsider his position regarding the teachings of the prior art, the combinations thereof, and the claims of the present invention.

Double Patenting.

The rejection of claims under the doctrine of obviousness-type double patenting as being unpatentable over claims 8, 10, 12-14, 21-23, 25-37, 34-36 and 38-40 of U.S. Patent Application No. 10/693,194 is maintained. The Applicants at this time have not provided a terminal disclaimer in this application, but will consider such a disclaimer in the event the claims in this application and the co-pending application are allowed, and in the form allowed would constitute obviousness-type double patenting.

Conclusion.

Applicants believe this is a thorough and comprehensive response to the rejections set forth by the Examiner in the most recent office action. Applicants respectfully submit that the present application is in condition for allowance. The Examiner is encouraged to contact the undersigned to resolve efficiently any formal matters or to discuss any aspects of the application or of this response. Otherwise, early notification of allowable subject matter is respectfully solicited.

Respectfully submitted,

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